

PATENT

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November 17, 2000
Date

Susan C. Rutledge
Susan C. Rutledge

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : John Jackson, Xichen Zhang and Helen Burt
Application No. : 09/181,582
Filed : October 28, 1998
For : POLYMERIC SYSTEMS FOR DRUG DELIVERY AND USES
THEREOF

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DEC 07 2000

TECH CENTER 1600/2800

Examiner : Edward J. Webman
Art Unit : 1617
Docket No. : 110129.416
Date : November 17, 2000

Box Non-Fee Amendment
Assistant Commissioner for Patents
Washington, DC 20231

REPLY TO OFFICE ACTION

Sir:

The present reply is responsive to the Office Action dated October 17, 2000 (Paper No. 12) in the above-identified application. The Office Action is directed to a single topic, namely, a supplemental election of species requirement. More specifically, the Office Action requires that a single water soluble polymeric species, among the two (2) polymer species recited in generic claim 13, be elected. In reply, Applicants elect methoxypolyethylene glycol (*i.e.*, MePEG), with traverse.

Initially, Applicants note that the two species identified by the Examiner, namely polyethylene glycol and methoxypolyethylene glycol, are related in that they are both water soluble polymers. The Examiner has not shown that these two polymers are separately classified by the U.S. Patent Office classification system, or that they have achieved a separate status in the

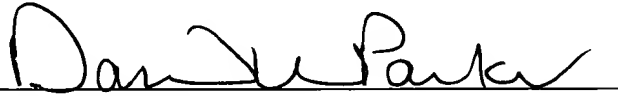
art. Furthermore, the Examiner has not shown that each species requires a different field of search. In fact, quite the contrary is almost surely true in regard to the field of search, in that it would seem practically impossible to search for one species without also searching for the other species, in view of their similar structures. Accordingly, Applicants respectfully request withdrawal of this supplemental election of species requirement, and examination of the full scope of claim 13.

37 C.F.R. 1.141 provides that an allowed generic claim may link a reasonable number of species embraced thereby. In the present case, claim 13 is generic to two species, as identified above. "Two" would certainly seem to be a reasonable number of species under 37 C.F.R. 1.141. Accordingly, in the event the Examiner does maintain the present election of species requirement, Applicant respectfully request that, in the event the Examiner finds the elected species to be patentable, the Examiner also consider the patentability of the full scope of claim 13 and all other elected claims.

Applicants would like to take this opportunity to reiterate their position taken in response to the initial restriction requirement (in Office Action dated December 29, 2000), to which the Examiner has not yet replied. That is, in response to the original restriction requirement, Applicants elected Group I, *i.e.*, claims 1-23 and 48-51, directed to a composition, where this election was made with traverse. Applicants continue to respectfully contend that the claims of Group II, *i.e.*, claims 24-30 and 52-60, should be considered along with the claims of Group I. The Examiner took the position that the process as claimed could be practiced with a materially different product such as a particulate. Applicants continue to respectfully disagree. The process as claimed is directed to using the composition of claim 1 to deliver drug to a subject. If the process as claimed were practiced with a materially different product, as suggested by the Examiner, then Applicants respectfully submit the process would not be performed according to its claimed language. Since the process for using the product as claimed could not be practiced with another materially different product, and since the product as claimed cannot be used in a materially different process of using that product, Applicants respectfully contend that restriction between the claims of Groups I and II is improper, and reconsideration and withdrawal of at least this portion of the restriction requirement is respectfully requested.

Consideration of the pending claims in view of the foregoing responses to the restriction requirement and election of species requirement is now requested.

Respectfully submitted,
Seed Intellectual Property Law Group PLLC



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Enclosures:
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In re application of: John Jackson et al.

Application No.: 09/181,582

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BOX NON-FEE AMENDMENT
 ASSISTANT COMMISSIONER FOR PATENTS
 WASHINGTON DC 20231

Assistant Commissioner for Patents:

Transmitted herewith is a **Reply to Office Action** in the above-identified application.

- ☒ Small entity status of this application under 37 CFR 1.9 and 1.27 has been established by a verified statement previously submitted.
- ☐ A verified statement to establish small entity status under CFR 1.9 and 1.27 is enclosed.
- ☐ A Petition for an Extension of Time for months is enclosed.
- ☐ A General Authorization Under 37 C.F.R. § 1.136(a)(3) is enclosed.
- ☒ No additional claim fee is required.
- ☐ The fee has been calculated as shown.

	(Col. 1)		(Col. 2)	(Col. 3)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST PREV. PAID FOR	PRESENT EXTRA
TOTAL	* 62	MINUS	** 62	0
INDEP.	* 6	MINUS	*** 6	0
EXTENSION OF TIME FEE				
TOTAL ADDITIONAL FEE				

SMALL ENTITY	
RATE	ADDITIONAL FEE
x 9	\$
x 39	\$
	\$
	\$

OR

OTHER THAN A SMALL ENTITY	
RATE	ADDITIONAL FEE
x 18	\$
x 78	\$
	\$
	\$

TOTAL

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment or the number of claims originally filed.

- ☐ Please charge my Deposit Account No. 19-1090 in the amount of \$_. A duplicate copy of this sheet is enclosed.
- ☐ A check in the amount of \$_ is attached.
- ☒ The Assistant Commissioner is hereby authorized to charge payment of the following additional fees associated with this communication or credit any overpayment to Deposit Account No. 19-1090. A duplicate copy of this sheet is enclosed.
- ☒ Any filing fees under 37 CFR 1.16 for the presentation of extra claims.
- ☒ Any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

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